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<p>(21) International Application Number: PCT/AU99/00598</p> <p>(22) International Filing Date: 23 July 1999 (23.07.99)</p> <p>(30) Priority Data:</p> <table> <tr> <td>PP 4869</td> <td>24 July 1998 (24.07.98)</td> <td>AU</td> </tr> <tr> <td>PP 5722</td> <td>4 September 1998 (04.09.98)</td> <td>AU</td> </tr> <tr> <td>PP 6597</td> <td>16 October 1998 (16.10.98)</td> <td>AU</td> </tr> </table> <p>(71) Applicant (for all designated States except US): NOBLE HOUSE GROUP PTY. LTD. [AU/AU]; 22 Molonglo Mall, Fyshwick, ACT 2609 (AU).</p> <p>(72) Inventors; and</p> <p>(75) Inventors/Applicants (for US only): DILLON, Jagmohanbir, Singh [AU/AU]; 9 Lamble Place, Oxley, ACT 2903 (AU). MOBBS, William, Leonard [AU/AU]; 7 Spensley Place, Wanniassa, ACT 2903 (AU).</p> <p>(74) Common Representative: NOBLE HOUSE GROUP PTY. LTD.; P.O. Box 1571, Woden, ACT 2606 (AU).</p>		PP 4869	24 July 1998 (24.07.98)	AU	PP 5722	4 September 1998 (04.09.98)	AU	PP 6597	16 October 1998 (16.10.98)	AU	<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report.</p>	
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<p>(54) Title: GUARDING NEEDLES IN IV PROCEDURES</p> <p>(57) Abstract</p> <p>A method and apparatus are disclosed for guarding both the IV needle and the sampling port needle in IV procedures, whereby the open end (38) of a needle guard (32) containing an IV needle is inserted into the open-end (40) of a tubular sampling port (20) so that the sampling port needle enters the guard (32). The guard (32) may be provided with a catch (70) that engages a corresponding aperture (74) in the port (20) when the guard is fully inserted into the port so that the guard is retained within the port against inadvertent removal.</p>												

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TITLE: GUARDING NEEDLES IN IV PROCEDURES**TECHNICAL FIELD**

This invention relates to methods and apparatus for mitigating the danger of

- 5 needle-stick and blood-splash during intravenous (IV) and similar medical procedures where a first needle is used to access a blood vessel and a second needle is used in a sampling port to draw-off samples of liquid obtained from the patient or delivered to the patient. The most common use envisaged for such methods and apparatus is in blood collection from blood donors, but the invention
- 10 is also applicable to other intravenous medical procedures such as renal dialysis and the sampling of liquids from body cavities. The invention is also concerned with the design and use of sampling ports and needle guards employed in any such procedure.
- 15 In this specification, 'needle-stick' refers to the pricking of a phlebotomist or other person with a used needle, while 'blood-splash' refers to the dripping or oozing of blood or other body liquid from a needle onto a person, or onto a surface that could come into contact with a person.
- 20 For convenience, this invention will be described with particular reference to procedures for collecting blood from donors but it will be appreciated that the invention is not necessarily confined to this context. Also for convenience, a sampling port may simply be referred to as a 'port'.

25 BACKGROUND

The collection of blood from donors, along with other IV procedures, involves the use of a needle assembly comprising a hypodermic needle that is connected to a flexible trailing tube via a needle hub. For convenience such needle assemblies may be referred to as IV needle assemblies.

- 30 Our prior Australian patent Nos 654464 and 695517 disclose a needle guard suitable for use with blood collection procedures employing IV needle assemblies. This guard is placed on the trailing tube so that the needle can be withdrawn from a patient directly into the guard by pulling on the tube. Once fully withdrawn into to guard, the needle is automatically locked within the guard so
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that it cannot be removed and so that it is rendered safe against needle-stick for handling and disposal. However, blood-splash can still occur through the open end of a guard housing a used needle. It is also known to form a needle guard around the needle and hub of an IV needle assembly so that the guard is

5 permanently attached to the needle assembly. In such guards, the unused needle can be extended from the guard for use and withdrawn into to guard after use but, again, there is the danger of blood-splash from the open end of a guard containing a used needle.

10 Since samples of blood must be taken for analysis at the time of blood collection, it is common practice to connect a sampling port to the trailing tube of the needle assembly and to dispose of the sampling port, needle and interconnecting tubing as a single item after use. The common port is simply a hollow moulded-plastic cylinder or barrel that has a closed base and an open top. A hollow needle is

15 mounted in the base so that it extends axially into the barrel, the butt of the needle being connected externally of the port to the trailing tube of the needle assembly. A rubber-like sheath normally covers the port needle. To collect a blood sample, a sealed vacuum phial with a rubber-like bung is pushed into the port and onto the sheathed needle so that the port needle penetrates its sheath

20 and the bung, causing blood (or other liquid) to be sucked into the phial from the tube of the needle assembly. When the phial is pulled out of the port, the needle is extracted from the bung, the bung reseals and the sheath springs back to cover the needle again.

25 While the barrel of the port is intended to shield the user from contact with the port needle, a user can inadvertently put a finger into the port and suffer needle-stick injury. It is also possible for blood to be exuded from the port needle and result in blood-splash contamination through the open end of the port. This can happen in various ways: blood can ooze through the pierced end of the sheath;

30 the sheath may not spring back and re-cover the needle allowing blood to flow from the needle point; if more than one sample is taken, compression of the sheath by each phial after the first will force blood from the bottom of the sheath into the base of the port.

To address the danger of blood-splash from the open end of a needle guard or a sampling port, and to mitigate the danger of needle-stick from the port needle, it is known to provide push-on caps for each type of device. An example of the use of a push-on cap for a needle guard is provided by Utterberg in US patent 5,112,311 and examples of the use of push-on caps for ports are provided by Coburn in US patents 4,784,650 and 4,932,418, Chen in US patent 5,752,936, Schmitt in US patent 5,259,392 and Broden in WO 88/05286. While effective, the use of such caps is bothersome and time-consuming for a phlebotomist.

10 Another known approach to mitigation of blood-splash from needle guards relies upon the use of textured surfaces or adsorbent pads in the guards near their open ends. This is exemplified by the above mentioned Utterberg patent and our Australian patents 654464 and 695517. Similarly, to inhibit blood forced from the bottom of a port-needle sheath from oozing along the screw-thread by which the 15 butt end of a sampling port needle is mounted in the base of the port, US patent 5,782,820 to Roland discloses the use of an adsorbent washer between the flange of the threaded needle butt and the exterior of the base of the port. Such a washer does not, however, mitigate blood-splash from the open end of the port, which is the principal danger.

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OBJECTIVES OF THE INVENTION

The invention seeks to provide means for mitigating the danger of blood-splash contamination from the open end of a guarded IV needle and/or from the open end of a sampling port.

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OUTLINE OF THE INVENTION

From one aspect, the present invention comprises a method of mitigating the danger of blood-splash contamination from the open end of a needle guard and/or from the open end of a sampling port, the method involving inserting the 30 open end of the needle guard into the open end of the port. Preferably, the guard is inserted so that the port needle enters the open end of the guard. The method may also include the steps of connecting the port-needle to the trailing tube of the needle assembly, taking samples from the trailing tube using vacuum phials,

withdrawing the IV needle into its guard, inserting the guard into the open end of the port and/or securing the needle guard in the port against unintended removal.

From another aspect, the invention may comprise a tubular needle guard having
5 retaining means adapted to retain the guard within a sampling port when the
guard is inserted into the port open-end first. Similarly, the invention may
comprise a tubular port having retaining means adapted to retain a tubular needle
guard that has been inserted into the port open-first. The retaining means may
comprise clips, catches, barbs or the like that are engaged by simply pushing the
10 guard into the port, but twisting or turning the guard in the port to effect retention
is also envisaged.

An adsorbent pad of material may be incorporated in the closed base of the port
around the butt of the port needle and the guard may be entered into the port so
15 that the open end of the guard is close to or presses upon the pad to reduce the
likelihood that blood will find its way from the open end of the guard into the barrel
of the port. In this way, substantially the full length of the port needle may be
inserted into the guard and the open end of the guard may be substantially closed
by the base of the port or by a pad therein. In addition to or instead of the pad,
20 the interior of the base of the port may be coated or treated to promote the
immobilisation and/or rapid clotting of blood.

It is desirable that a separate guide means are formed in the barrel of the
sampling port to accommodate and guide a phial and a guard during insertion
25 into the port, at least the guide means for the phial including stop means that
limits the inward travel of the phial into the port. This enables the limit for phial
penetration to be set so that the bung of the phial cannot contact the base of the
port or an adsorbent pad fitted in the base, since such contact may contaminate
the end of the bung with blood or other liquid on the pad or base of the port. On
30 the other hand, the use of separate guide and/or stop means allows a guard to be
entered further into the port than a phial, permitting the end of the guard to be
positioned in contact with or in close proximity to the base of the port or a pad
fitted therein. It is also desirable to limit the penetration of a phial into the port to
ensure that the needle sheath is not damaged by excessive compression.

Conveniently, the guard can have a generally rectangular section and the phial a smaller generally circular section, and the guide means can comprise grooves or channels formed in the wall of the barrel of the port that are shaped and dimensioned so that phials and guards are guided and stopped differently.

5

The materials employed for the port pad can be fibrous or foamed, synthetic and/or natural, so long as they are highly wettable and capable of rapidly absorbing and retaining substantial quantities of aqueous liquids (in relation to their dry weight or volume). Examples of suitable materials are cellulose fibres

10 (natural or synthetic), plasters, clays, fired or unfired but unglazed ceramic materials, foamed materials of synthetic or natural components. Such materials may be formed into washer-like discs and pressed and/or glued into the base of the sampling port so that they are retained therein. If desired, the internal surface of the port and/or the external surface of the internal needle boss can include a

15 recess or ridge to assist in retaining the discs.

20

Suitable coatings can be formed from a variety of natural or synthetic materials applied as paints or slips which dry to form porous and/or hydrophilic layers on the interior of the sampling port, preferably at or near the base thereof.

The treatments envisaged include the formation of etched or textured surfaces on the interior of the sampling ports, preferably near their closed ends were first contact with blood or other fluid which has leaked from the port needle is most likely. The etching may be effected by acid etching the exterior of the core used in

25 moulding the port, or it may be effected by treating the interior of the port with acids, plasma discharges or the like.

30

The pad materials and/or the interior of the port may be impregnated, coated or otherwise treated with fine particulate minerals, such as the silicates of, sodium, potassium, magnesium and/or aluminium, titanium dioxide, diatomaceous earth. Fine powders of fired or unfired clays, cementicous materials or the like may also be employed. Preferably, such mineraliferous materials have particle sizes of less than 20 μ , more preferably less than 5 μ and most preferably of sub-micron dimensions (ie, less than 1 μ). As an alternative – or in addition – to the use of

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mineraliferous materials, this invention also envisages the use of intrinsic clotting pathways. For example, the pads may incorporate thrombin, heparinase and/or fibrinogen, or various peptides and proteins.

DESCRIPTION OF EXAMPLES

5 Having broadly portrayed the nature of the present invention, exemplary embodiments will now be described with reference to the accompanying drawings, in which:

Figure 1A is a diagram showing an IV needle assembly, guard, sampling port and phial being used to collect blood.

10 Figure 1B is a diagram showing the system of Figure 1A being used to collect blood samples.

Figure 1C is a diagram showing the system of Figure 1A after collection of samples and withdrawal of the IV needle guard into the sampling port.

15 Figure 1D is a diagram of the system of Figure 1A after the needle guard has been inserted into the sampling port.

Figure 2 is an enlarged perspective view of the sampling port employed in the system of Figures 1A-1D, showing a sampling phial aligned therewith, the sampling port being shown in longitudinal section taken on plane 2-2 of Figure 3.

20 Figure 3 is an enlarged perspective view of the sampling port and an aligned needle guard of the system of Figures 1A-1D.

Figure 4 is an enlarged perspective view of the sampling port and phial of the system of Figures 1A-1D, with the phial fully inserted in the port.

25 Figure 5 is an enlarged perspective of the port of Figures 1A-1D with the needle guard fully inserted therein.

Figure 6 is an enlarged longitudinal section of portion of the port and phial of Figure 4 taken on section plane 6-6 of Figure 4.

Figure 7 is an enlarged longitudinal section of portion of the port and guard of Figure 5 taken on section plane 7-7 of Figure 5.

5 Figure 8 is a perspective view of a second example of a guard and port combination showing the guard aligned with the port, but with both the needle assembly and the port-needle omitted for clarity.

Figure 9 is a sectional view, taken on plane 9-9, of the port of Figure 8 with the guard of Figure 8 fully inserted into the port.

Figure 10A is an end view of the guard and port of Figure 9 taken on plane 10-10 of Figure 9.

10 Figure 10B is an end view of the port of Figure 9 taken on plane 10-10 of Figure 9, with a phial substituted for the guard of Figure 10A.

Figure 11 is a perspective view of a sampling port and guard, which comprise a third example of a guard and port combination, but with both the needle assembly and the port-needle omitted for clarity.

15 Figure 12 is a perspective of the of a sampling port and guard, which comprise a fourth example of a guard and port combination; with both the needle assembly and the port-needle omitted for clarity.

Figure 13 is a perspective view of portions of a sampling port and guard, which comprise a fifth example of a guard and port combination, but with both the needle assembly and the port-needle omitted for clarity.

20 A system 10 for collecting blood and blood samples from blood donors is shown in Figures 1A-1D. Figure 1A shows the blood collection under-way; that is, blood is flowing in the blood-line 12 to collection bags (not shown), cut-off clamp 14 being open and the needle 16 remaining the donor's arm 18. Figure 1B shows 25 system 10 when blood collection has been completed, clamp 14 is closed to seal blood-line and, preferably, blood-line 12 is severed immediately down-stream of clamp 14. Samples can now be drawn off using a sampling port 20 and vacuum phials 22 without any fear of contaminating the collected blood.

In this example, the needle assembly 24, comprises the needle 16, a needle hub 26 and a trailing tube 28 that is connected to a Y-joint 30 which is, in turn, connected to blood-line 12. A needle guard 32 of the type that slides on trailing tube 28 is shown partially covering needle hub 26, but it will be appreciated that

5 guard 32 can be of the type that does not slide on tube 28 but completely encloses and permanently captures needle hub 26. Sampling port 20 is shown connected to Y-joint 30 by a sampling tube 34, but tube 34 can be dispensed with if spigot 36 extending from the base of port 20 can be inserted directly through a membrane or valve seal into joint 30. Normally, spigot 36 is formed by the butt

10 end of the port-needle (to be described below).

After sufficient samples have been collected, needle 16 is withdrawn from arm 18 directly into guard 32 by pulling on trailing tube 28 while holding the guard, needle 16 and hub 26 being automatically locked inside guard 32 so that the point of needle 16 is not accessible. Immediately after withdrawal of needle 16 into guard

15 32, the guard is held in one hand by the phlebotomist and turned so that its open end 38 is aligned with the open top 40 of port 20, which is held in the phlebotomist's other hand. At this point, system 10 is as shown in Figure 1C and, in partial enlargement, in Figure 3. Finally, guard 32 (with needle 16 encased therein) is pushed home into port 20 and needle assembly 24, guard 32 and port

20 20 (with associated tubes 28, 34 and (portion of) 12, together with Y-joint 30) are disposed of in a bag (not shown) for contaminated waste. The situation immediately prior to disposal is shown in Figure 1D and in partial enlargement in Figure 5.

Figures 2, 4 and 6 illustrate the port 20 and phial 22 in greater detail, Figure 2

25 showing phial 22 as it is about to be inserted in port 20, Figure 4 showing phial 22 fully inserted in port 20 and Figure 6 being a partial longitudinal section of the fully-inserted phial. Phial 22 is a standard and well-known product, having a transparent glass or plastic test-tube like body 42 fitted with a pierceable rubber-like bung 44 and being evacuated. Sampling port 20 has an elongate barrel-like

30 body 46 with open top 40 and a closed base 48, the top 42 having an outwardly extending flange 50. Spigot 36 extends outwardly from base 48 to connect with sampling tube 34, spigot 36 being moulded onto the butt end of the port needle 52 and being screwed into an internally threaded boss 54 (see particularly Figure

6) formed in the centre of base 48. Port-needle 52 is encased in a rubber sheath 56, shown extended but with its top cut away in Figure 2 and shown compressed and in section in Figure 6. An adsorbent pad 58 is located in the bottom of port 20 on the inner surface of base 48 so as to surround the bottom of needle 52 and

5 sheath 56.

The barrel 46 of port 20 has opposed semi-cylindrical longitudinally-extending wall portions 60 that, internally, form guide channels 62 (Figure 2) for guiding phials 22 as the phials are inserted into and withdrawn from port 20. Wall portions 60 and phial-guides 62 terminate in shoulders 64 near base 48 that serve to limit

10 the penetration of a phial into the port so that the bung 44 cannot contact pad 58. (See Figure 6).

Figures 3, 5 and 7 illustrate the interaction of guard 32 and port 20 in more detail. [This guard is substantially as disclosed in our aforementioned patents and reference to those patents should be made with regard to its function in relation to

15 needle assembly 24.] Opposing sides of port barrel 46 form a pair of flat longitudinally extending wall portions 64 running substantially the full length of barrel 46, flats 64 being arranged in quadrature to cylindrical portions 60 of the barrel. Internally, wall portions 64 form a pair of opposed rectilinear grooves or guard-guide channels 66 (Figures 2 and 7) which, between them, are adapted to

20 slidingly guide and accommodate the needle guard 32. The distance between opposing guard-guides 66 is greater than that between opposing phial-guides 62, so that guard 32 cannot enter or be guided by phial guides 62. However, to assist initial entry of guard 32 into port 20, the upper portion of barrel 46 is diametrically enlarged, as indicated at 68. This allows guard 32 to be inserted into enlargement

25 68 via port end 40 in any orientation and then rotated about its longitudinal axis to align guard 32 with guard-guides 66. It should be noted that the circumferential width of guard channels 66 is insufficient to allow phials 22 to enter them or to be guided by them. Thus, by means of guides 66, a guard 32 can be fully entered into port 20 so that its open end 38 contacts pad 58 at the bottom of the port (see

30 Figure 7), but a phial 22 cannot be entered so far into port 20 because its travel is limited by abutment of its bung 44 with shoulders 64 on phial-guides 62. This prevents bungs 44 of phials 22 from contacting pad 58 and being contaminated by blood in or on the pad.

In this first example, the retaining means that retain guard 32 in port 20 simply comprise a tooth-like catch 70 on at least one of the narrow sides 72 of guard 32, catch 70 being adapted to enter a corresponding aperture 74 near the top of either guard-channel 66 of port 20. While catches 70 may be formed on both

5 sides of guard 34, moulding considerations associated with the particular guard disclosed in our above mentioned Australian patents, make it convenient to employ only one catch and to place that catch on the side of the guard that is not hinged. Since apertures 74 are formed on each side of port 20, guard 32 will be retained in the 20 in either of the ways it can be oriented in guide channels 66. It

10 will be appreciated that essentially the same form of retaining means would result if internally facing tooth-like catches were formed on the inside of guard channels 66 and corresponding apertures were formed in the sides of guard 32, and that modification (among others) is envisaged by this invention. It will also be appreciated that the walls of guard 32 are sufficiently flexible so that they will

15 deflect to allow catches 70 to enter port 20 and that barrel wall 46 of port 20 is sufficiently stiff so that, once catches 70 have engaged apertures 74, it will not be easy to squeeze cylindrical guide portions 60 together between the fingers sufficiently to release catches 70 from apertures 74.

Adsorbent pad 58 (Figures 2, 6 and 7) is shaped to fit the bottom of base 48 of port 20, which in this example is generally rectangular (see Figures 2-5), the pad having a central hole that fits closely around the butt 36 and sheath 56 of port needle 52. Pad 58 may be glued in place or held in place by friction. If desired, protrusions (not shown) may be formed on the inside of barrel 46 near base 48 to retain pad 58 in position. Pad 58 can be formed from highly porous cellulose

25 material not unlike blotting paper and treated with sub-micron particles of TiO₂ and/or clay, the particles adhering to individual fibres rather than creating a filling or size that reduces the porosity of the pad. In addition to or instead of pad 58, the internal surfaces of port 20 near base 48 can be coated or treated with materials known to promote blood-clotting or to assist in immobilising the flow of

30 blood or other aqueous liquids on or along surfaces. A simple treatment may be effected by etching the surface of the internal mould from which port 20 is formed, or by the use of plasma discharge within port 20. Some coatings that may be used have already been indicated in the Outline of Invention above.

The second example of the present invention shown in Figures 8 and 9 illustrates the use of an alternative form of retaining means to that of the first example, the needle guard 100 of this example being essentially the same as that (32) of the first example except that it does not have tooth-like catch 70 of that example.

- 5 Guard 100 can be formed by clipping together two similar sub-members 100a and 100b, each having three side recesses 101 on one of their narrow side faces 102 to take corresponding clips (not shown here) on the other narrow side face of the other sub-member, the engagement of the clips and recesses 101 holding the sub-members together. In this example, sampling port 104 is also of tubular form,
- 10 but of octagonal section, having a base 106 that has a central internally-threaded boss 108 adapted to take the threaded spigot of a sampling-port needle (not shown). As in the first example, port 104 has an open top 110 surrounded by a flange 112. Immediately below flange 112 are formed four evenly spaced inwardly facing resilient catches 114 that are adapted to enter any one of
- 15 recesses 101 of a guard 100 that is inserted into port 102. Thus, in this example, recesses 101 and catches 114 form the retaining means. Preferably, as shown in Figure 9, the guard is fully inserted into port 104 and the port is so dimensioned that one of catches 114 can enter the central one of recesses 101 when the guard is so inserted.
- 20 With particular reference to Figures 10A and 10B, port 104 has four internal longitudinally and radially extending ribs 116 that define a pair of channels 118 extending longitudinally between them within which guard 100 can be slidingly guided into port 104 in any one of four orientations so that a respective pair of catches 114 can engage both central recess 101 of guard 100 (see Figure 9).
- 25 The inner faces 116a of ribs 116 also serve to guide a phial 118 – see Figure 10B – into port 100, allowing phial 118 to be removed without the danger of the bung 120 of the phial snagging catches 114. In this case, the depth of penetration of the phial and guard 100 are both limited by a set of four short ribs 122 upstanding from the inside of the base of guard 104 and extending inwards of guide ribs 116
- 30 (see Figure 9). Instead of including a pad at the base of port 104, the inner walls of the port and the exposed surfaces of ribs 116 and 122 near the bottom of the port are roughened and/or coated – as indicated at 124 – to immobilise any blood or droplets of other liquid that comes into contact therewith. It will be appreciated

that, by disposing bottom ribs 112 in between longitudinal guide ribs 116, they will still serve as stops for phial 118 but not as stops for guard 100, so that guard 100 can penetrate to the base of port 104 as in the first example.

The third example is illustrated in Figure 11 and comprises a tubular needle

5 guard 150 of generally rectangular section and a tubular port 152 of generally circular section. Port 152 includes a cylindrical barrel 154 that has a flanged open end 156 and a closed base 158 having a threaded boss 160 into which the butt of a sampling needle (not shown) can be screwed. In this case, the retaining means comprises a bayonet-type coupling between guard 150 and port 152, guard 150

10 having a pair of lateral protrusions 162 intermediate of its ends (only one of which is shown in Figure 11) that can enter corresponding radial slots 164 (only one of which is shown) formed in flange 166 of port 152. Slots 164 allow protrusions 162 to enter a pair of circumferentially extending slots 168 (only one of which is shown) formed in the upper part of the barrel 154 of port 152. A tooth or catch

15 170 is formed on the underside of flange 166 on each side of slots 164 to retain protrusions 162 against removal, once they have been entered laterally into slots 168 by twisting guard 150 relative to port 152.

Figure 12 illustrates the fourth example of this invention wherein the retaining means on the guard comprise a pair of laterally-extending and rearwardly-facing

20 teeth or catches 180 formed on the outside of open end 182 of a needle guard 184. Needle guard 184 can be otherwise similar to the guard disclosed in our afore-mentioned prior patents. The coacting retaining means on the corresponding port 186 comprises an indented catch-band 188 formed around barrel 190 of port 186 near its base 192. While guide ribs or slots may be

25 provided on the inside of barrel 190 to separately guide guard 184 and sampling phials (not shown) as in the second example, it is preferred in this case to make the guard and the phials of substantially the same lateral dimension so that they will both slide smoothly into barrel 190 in any angular orientation about their respective longitudinal axes. Conveniently, then, catch-band 188 serves as a stop

30 to limit the inward travel of a phial but allows the open end 182 of guard 184 to be pushed beyond band 188 until teeth 180 are engaged with the band 188. Again, it is desirable that the walls of guard 184 have sufficient flexibility to deform sufficiently to allow teeth 180 to travel beyond catch band 188. In an alternative

arrangement, a plurality of small ratchet-like teeth can be formed on the end of guard 184 instead of the single tooth 180 on each side and a series of narrow corresponding catch-bands can be formed in the inside of port barrel 190 instead of the single large band 188.

5 Figure 13 illustrates the fifth example, involving a tubular guard 200 and a tubular sampling port 202. In this case, guard 200 is one in which the needle mount (not shown) is captured therein, the IV needle (not shown) being extended from the guard for use and withdrawn back into the guard 200 after use. In this case, guard 200 has an outer dimension that is substantially smaller than the internal 10 diameter of port 202 and the phials (not shown) intended for use in the port.

The retaining means of this example comprise a pair of clips 204 that extend axially from the end face 206 of guard 200 so as to be adapted to engage a plurality of corresponding pairs of membrane-slots 208 formed in the flat base 210 of port 202. Each membrane slot is covered by a thin membrane or 'flash' 15 that can be readily punctured or penetrated by a clip 204. Thus, when guard 200 is pushed right into port 202 and rotated to align clips 204 with a pair of slots 208, it can be pushed a little further to drive clips 204 through slots 208 so that they retain guard 200 in port 202. If desired, at least the end portion of guard 202 may have a rectangular shape (as in the other examples) and port 202 may be 20 provided with internal ribs (as in the second example) so that clips 204 are correctly aligned with a pair of slots 208 as guard 200 is pushed into port 204. This has the advantage of preventing clips 204 being broken off or damaged by excessive pressure before they are aligned with slots 208.

Those skilled in the art will appreciate that many other examples and variations of 25 the application of the principles of the present invention can be made without departing from the scope of the invention as defined in the following claims. For instance, in the example of Figure 13, clips like those shown on the needle guard (but facing outwardly) can be formed to upstand from the base of the port so as to enter the open end of a guard such as that of the first example and to retain the 30 guard in the port. If desired, a single clip of circular form may be used. In any event, such a clip or clips can also serve to limit the penetration of the phials into the port.

CLAIMS

- 1 A method of mitigating the danger of blood-splash contamination from the open end of a tubular needle guard into which a used medical needle has been withdrawn, for mitigating the danger of blood splash from the open end of a tubular sampling port having a used sampling needle mounted therein, or for mitigating the danger needle-stick injury from the sampling needle mounted within the sampling port, the method comprising the step of inserting the open end of the needle guard into the open end of the sampling port.
- 10 2 A method according to claim 1 wherein the needle guard is inserted into the sampling port so the sampling needle enters the open end of the guard.
- 15 3 A method according to claim 1 or 2 including the step of securing the needle guard within the sampling port against unintended removal or separation therefrom.
- 20 4 A method according to claim 1, 2 or 3 wherein the sampling port has a closed base on which the sampling needle is mounted so as to extend axially into the port, and wherein an adsorbent pad is located within the sampling port against the base so as to surround the sampling needle, the method including the step of inserting the needle guard into the sampling port so that the open end of the needle guard juxtaposes the adsorbent pad.
- 25 5 A method according to claim 1, 2 or 3 wherein the sampling port has a closed base on which the sampling needle is mounted so as to extend axially into the port, and wherein an adsorbent pad is located within the sampling port against the base so as to surround the sampling needle, the method including the step of:
 - 30 inserting a vacuum phial into the port to draw a liquid sample from the sampling needle, said vacuum phial having a bung at one end that is capable of being pierced by the sampling needle,
 - ensuring that the phial does not extend into the port sufficiently to allow said bung to contact said pad,
 - removing the phial with its sample from the port, and

inserting the needle guard into the sampling port so that the open end of the needle guard juxtaposes the adsorbent pad.

- 6 A method of reducing the risk of blood-splash contamination during IV procedures where an IV needle is inserted into a patient or donor and is connected to a tubular sampling port, the sampling port having an open top and a closed base and having a sampling needle is mounted on the base so as to extend into the port for use with evacuated sample phials inserted into the sampling port, the method comprising the steps of:
 - 5 withdrawing the IV needle from the patient into a tubular guard through an open end of the guard,
 - 10 inserting the guard open-end first into the open top of the sampling port so that the sampling needle enters the open end of the guard, and
 - 15 securing the guard within the sampling port against inadvertent removal or separation.
- 7 Apparatus for use with intravenous (IV) medical procedures comprising:
 - an IV needle assembly including a hollow medical needle and a trailing tube in fluid connection with said needle,
 - 20 a tubular needle guard having an open end into which the needle can be withdrawn after use so that the needle is shielded by the guard against external contact,
 - 25 a tubular sampling port having an open top end, a closed bottom end, a lateral dimension sufficient to permit said needle guard to be slidably entered into the port open-end-first,
 - 30 a hollow sampling needle mounted in said base of the port so as to extend axially into the port, the sampling needle being externally connectable to said trailing tube so that samples of liquid from said tube can be drawn off using the sampling needle, and
 - 30 retaining means operable between said guard and said port to retain the guard within the port when the guard is entered into the port open-end-first so that the sampling needle enters the open end of the guard.

16

8 A tubular needle guard for use in the method of claim 3, characterised in that the guard includes retaining means adapted to engage the sampling port, when the guard is inserted therein and to retain the guard in the sampling port against inadvertent removal or separation.

5

9 A needle guard according to claim 8 wherein said retaining means comprises a pawl-like catch on or in said guard adapted to engage a corresponding protrusion or recess formed on or in the sampling port, or wherein said retaining means comprises a protrusion or recess formed on or in the guard 10 adapted to engage a corresponding pawl-like catch on or in the sampling port.

10 A needle guard according to claim 8 wherein said retaining means comprises a laterally extending protrusion or recess on the needle guard adapted for rotary or twisting engagement with a corresponding recess or protrusion 15 formed on or in the sampling port.

11 A sampling port for use in the method of claim 3 characterised in that the sampling port has retaining means adapted to engage the needle guard, when the guard is inserted into the sampling port, and to retain the guard in the 20 sampling port against subsequent inadvertent removal or disengagement.

12 A sampling port according to claim 11 wherein said retaining means comprises a pawl-like catch on or in said sampling port adapted to engage a corresponding protrusion or recess formed on or in the guard, or wherein said 25 retaining means comprises a protrusion or recess formed on or in the sampling port adapted to engage a corresponding pawl-like catch on or in the guard.

13 A sampling port according to claim 11 wherein said retaining means comprises a laterally extending recess or protrusion on the sampling port adapted 30 for rotary or twisting engagement with a corresponding protrusion or recess formed on or in the guard.

14 A sampling port for use in the method of claim 1 or 2 and having a tubular body that has a closed base and an open top and having a sampling needle

mounted on the base so as to extend into the body, the sampling port being characterised in that:

stop means are provided therein adapted to limit the depth to which an evacuated sample phial can be entered into the body such that said phial cannot 5 contact the base of the port.

15 A sampling port according to claim 14 wherein said stop means are arranged so as to permit a needle guard to be entered into the port sufficiently to permit contact between the guard and the base of the port.

10

16 A sampling port according to claim 14 or 15 comprising:

first guide means adapted to guide a tubular sampling phial coaxially within the sampling port upon sliding insertion of the sampling phial into the open end of said port,

15 second guide means adapted to guide said needle guard within said body upon sliding insertion of the guard within said port so that the sampling needle enters the open end of the guard, and

20 retaining means associated with said second guide means adapted, upon insertion of the guard into the port to engage the needle guard and to retain said guard within the port against inadvertent removal or separation

17 A sampling port for use in the method of any one of claims 1-3 and comprising:

25 a body having a closed base that forms the bottom of the sampling port, a tubular wall with an outwardly flanged open top that forms the open top of the sampling port, and a central axis,

means for mounting the sampling needle on or in said base so that the needle projects axially into said body,

30 a first pair of opposed, diametrically spaced and axially extending channels formed in said wall, each channel of said first pair being of outwardly curved section such that a tubular sampling phial of circular section will be axially guided by said channels upon insertion of the phial into the body of the sampling port, said first pair of channels forming said first guide means and the channels of said first pair being diametrically spaced from one another by a first distance,

a second pair of opposed, diametrically spaced and axially extending channels formed in said wall in quadrature with said first pair of channels, the channels of said second pair being diametrically spaced from one another by a distance that is greater than said first distance, said channels of the second pair

5 forming said second guide means and being adapted to guide the sides of a needle guard upon insertion of the guard into the body of the sampling port.

18 A sampling port according to any one of claims 11 to 17 wherein liquid immobilising means are formed within the port on or near the base thereof.

10 19 A sampling port according to claim 18 wherein said immobilising means comprises a pad of material that is wettable by said liquid, said pad being located within the sampling-port so as to surround the sampling-port needle on said base.

20 A sampling port according to claim 19 wherein said pad is formed from fibrous porous and liquid adsorbent material.

15 21 A sampling port according to claim 19 or 20 wherein said pad is formed from a synthetic open-cell foamed material.

22 A sampling port according to claim 19 wherein said pad is formed from a porous ceramic material.

23 A sampling port according to claim 18 wherein said immobilising means

20 comprises an area of the internal surface of the sampling-port surrounding the sampling-port needle at or near the base of the sampling-port, said area being coated, treated or roughened so as to promote the adherence of said liquid drops thereto.

24 A sampling-port according to any one of claims 18-23 wherein said immobilising means is adapted to promote rapid clotting of blood.

An IV set including for use in the method of claim 1 and comprising a needle guard as claimed in any one of claims 8-10 and a sampling port as claimed in any one of claims 11-24.

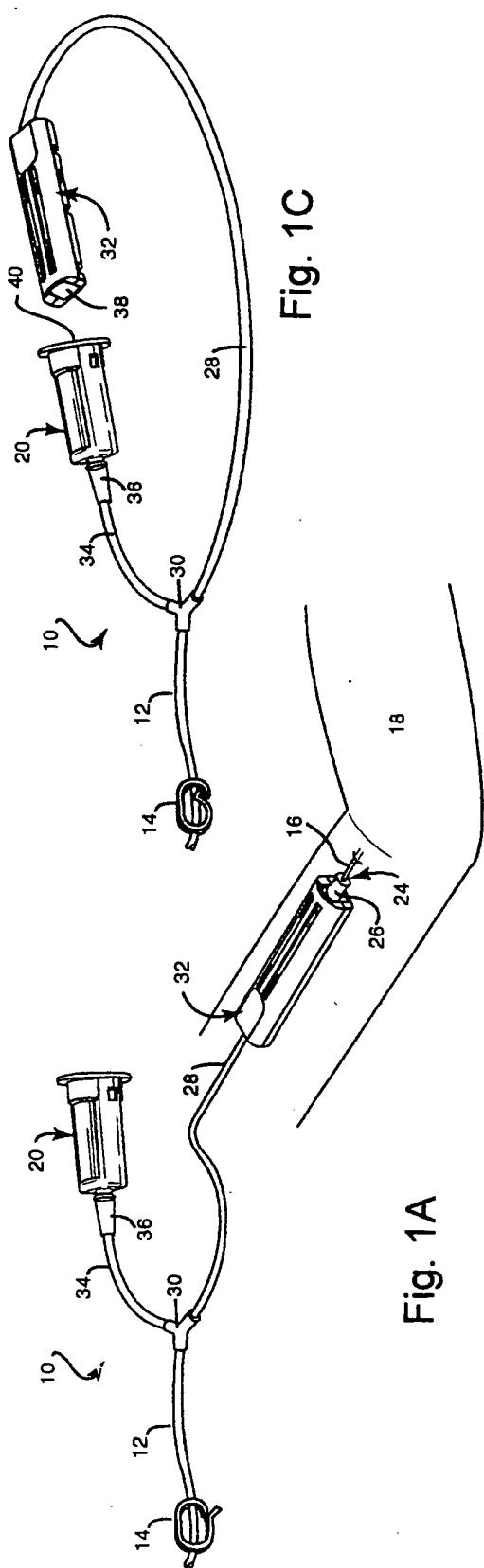
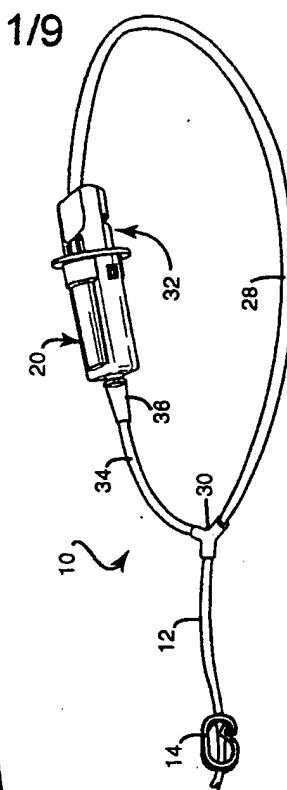
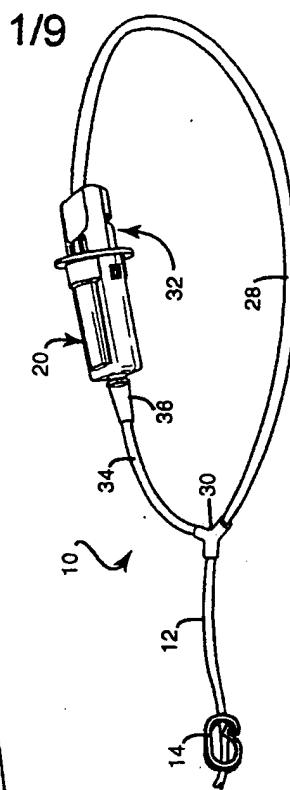
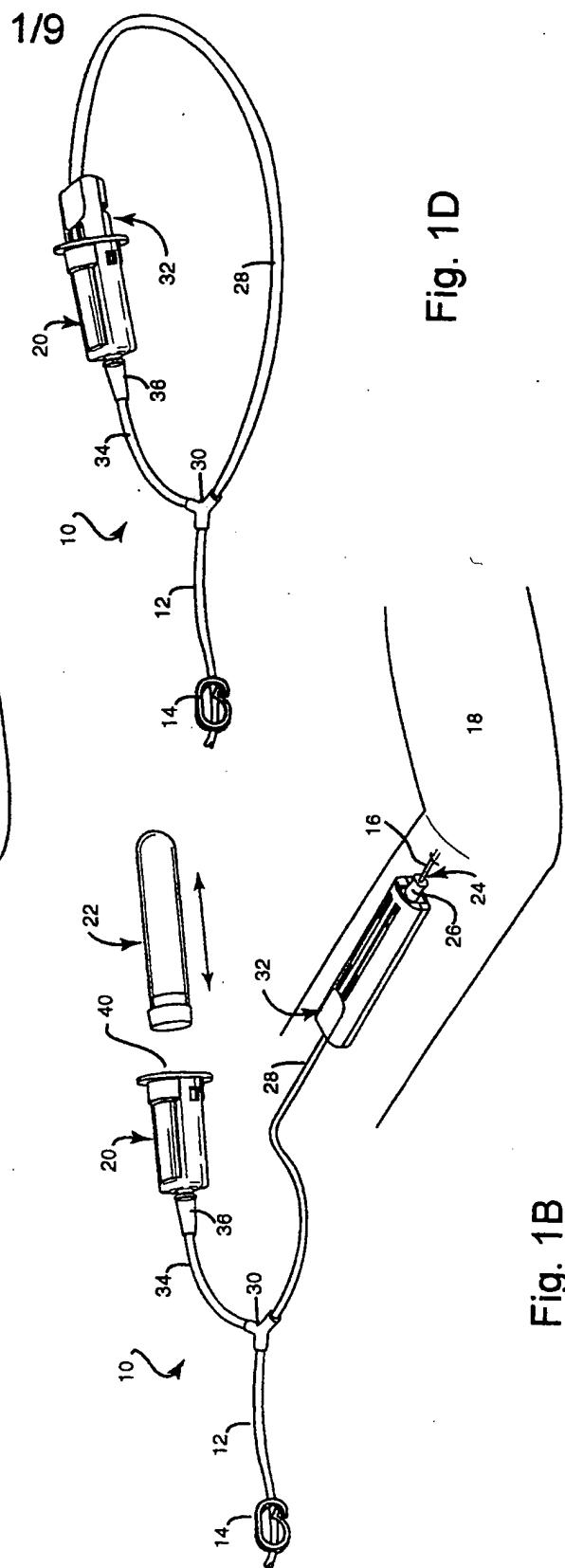
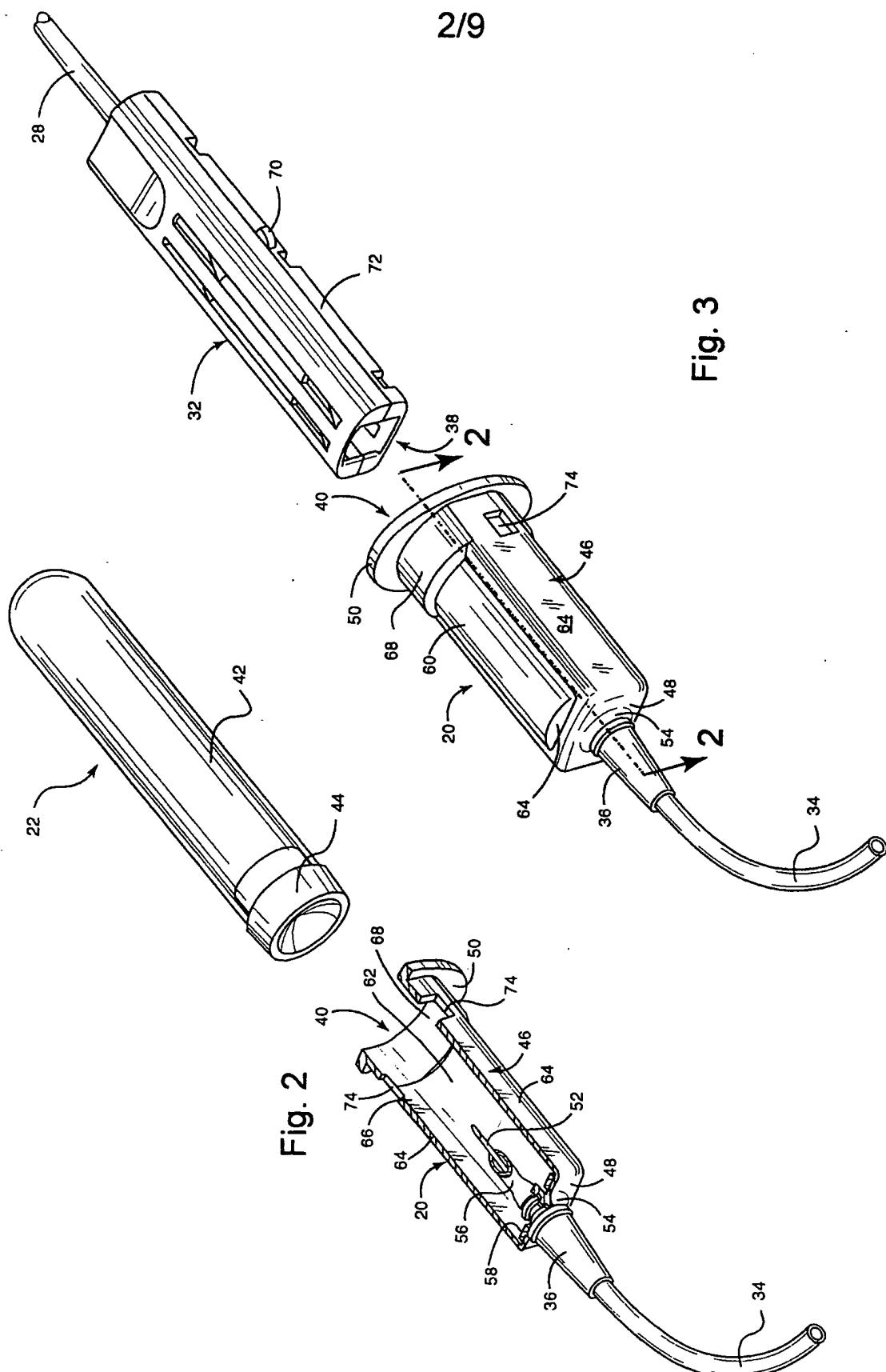


Fig. 1C





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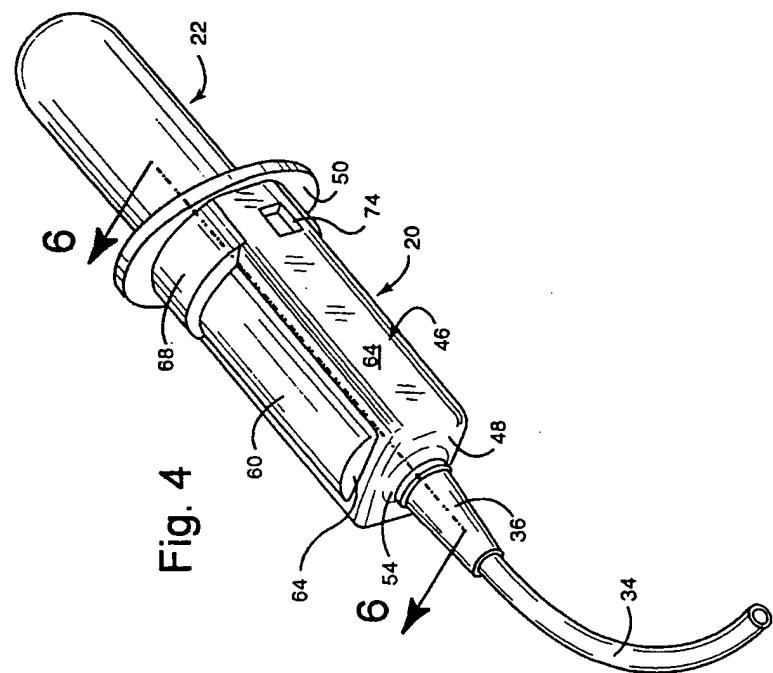


Fig. 4

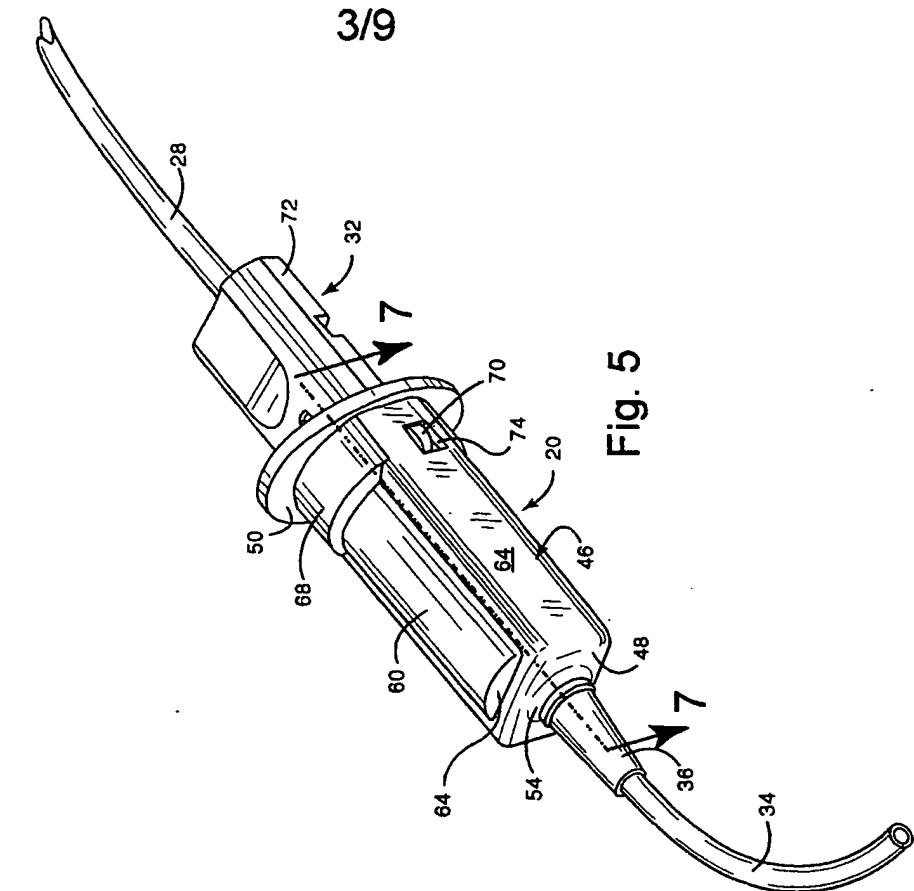


Fig. 5

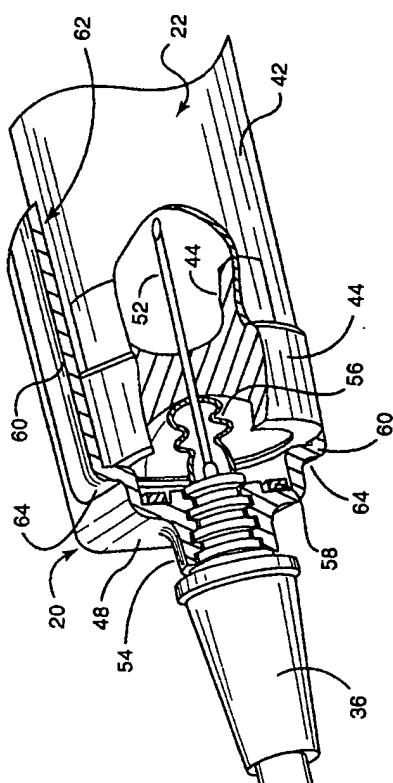


Fig. 6

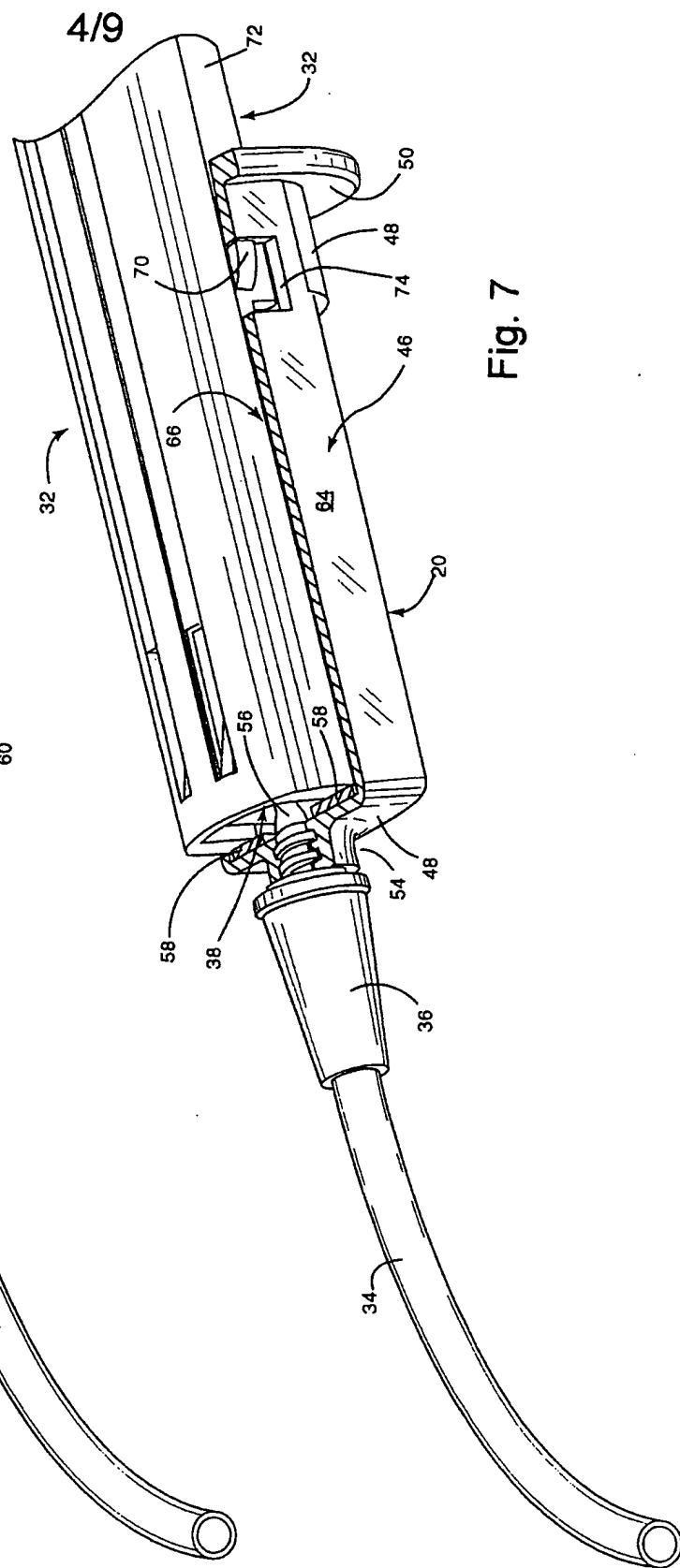


Fig. 7

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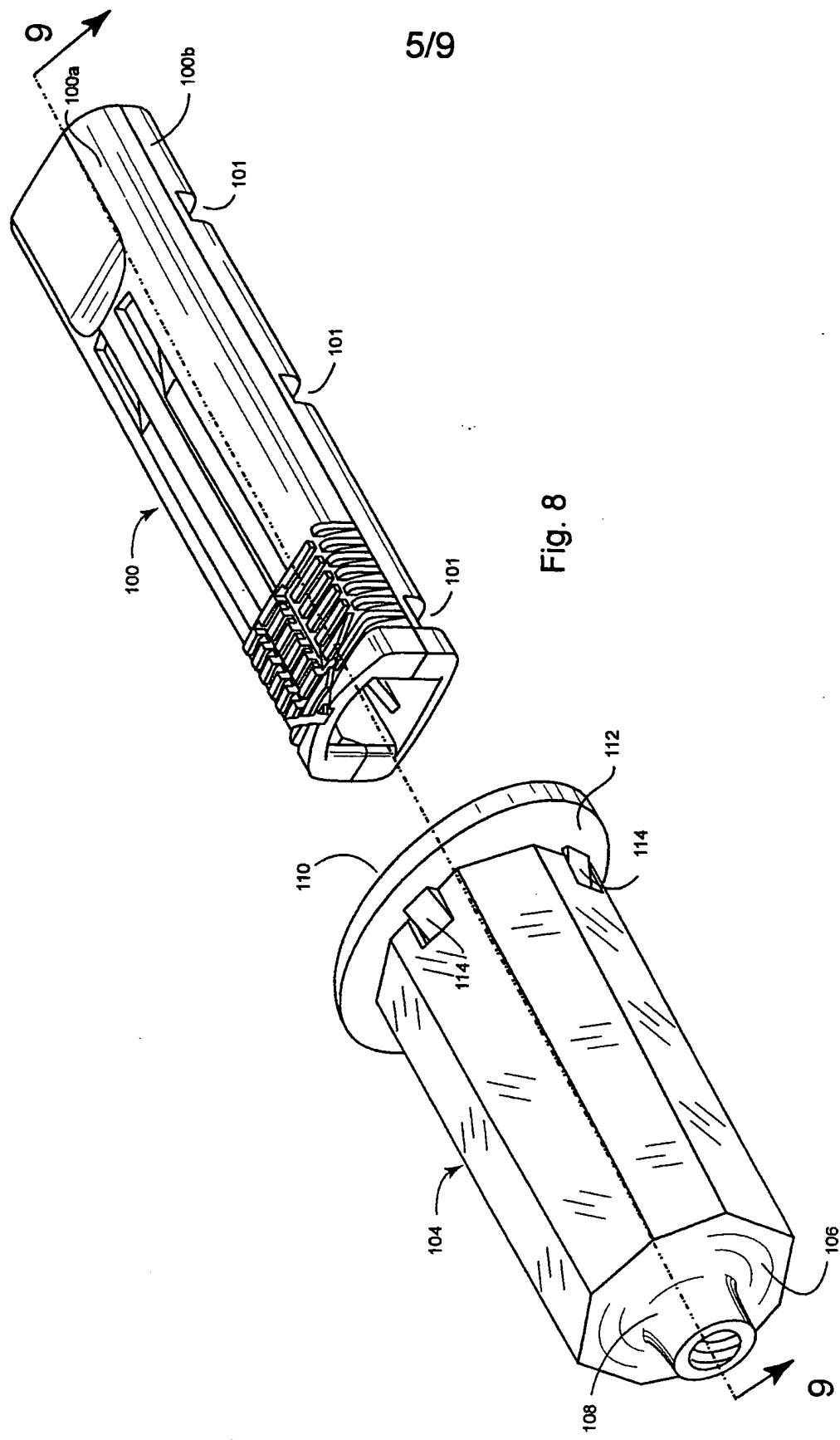


Fig. 8

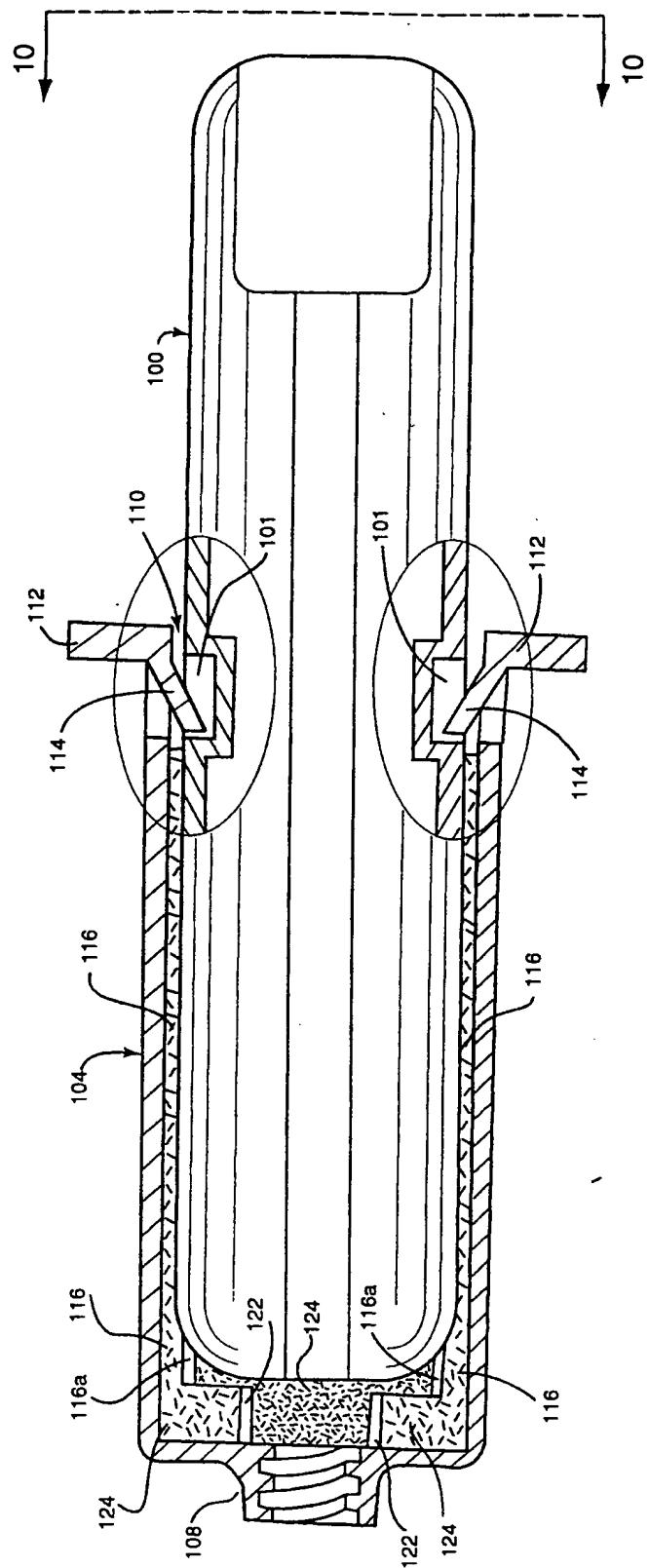


Fig. 9

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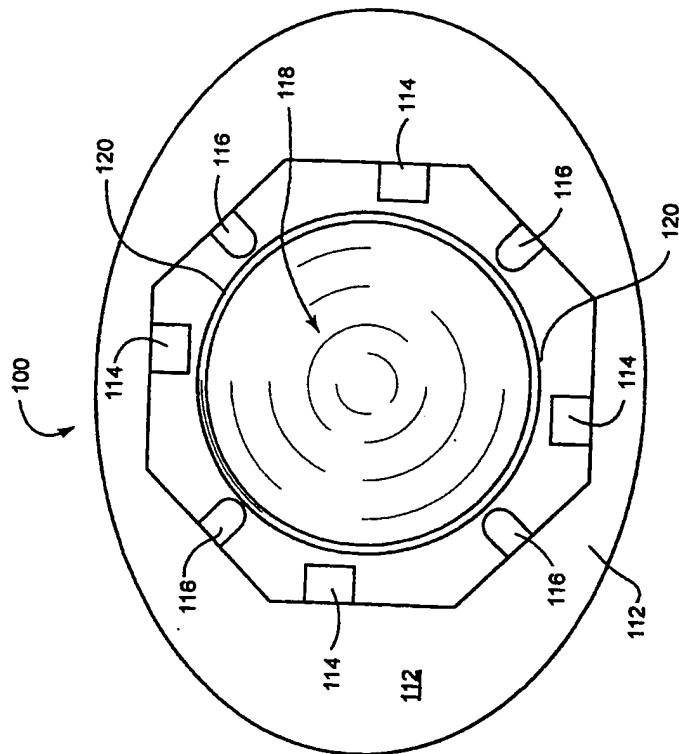


Fig. 10B

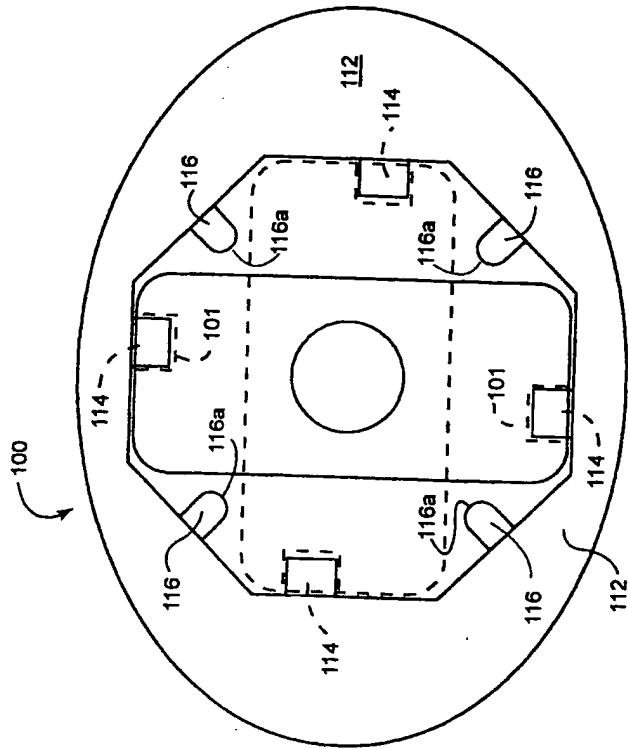


Fig. 10A

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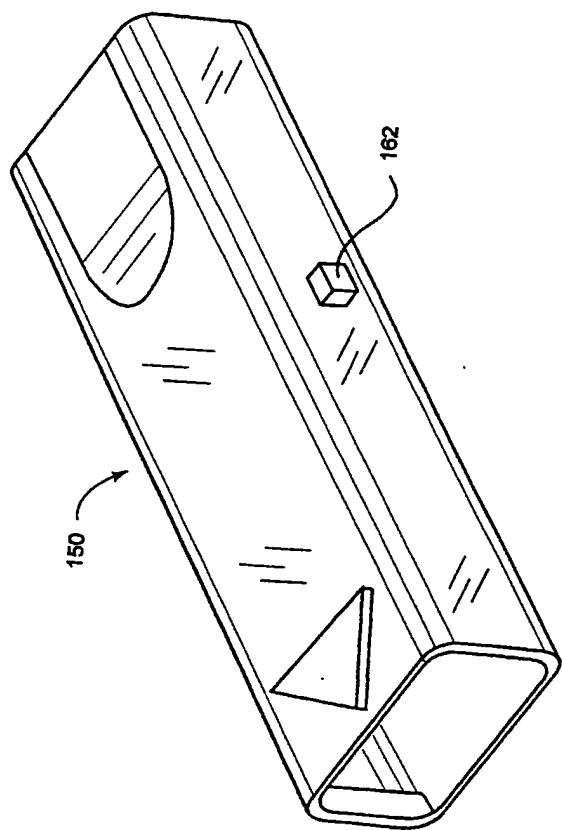
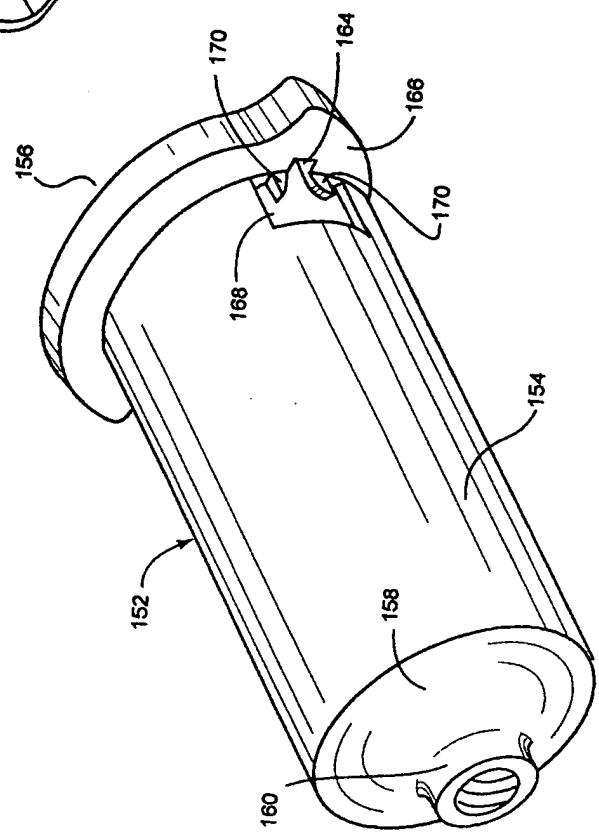


Fig. 11



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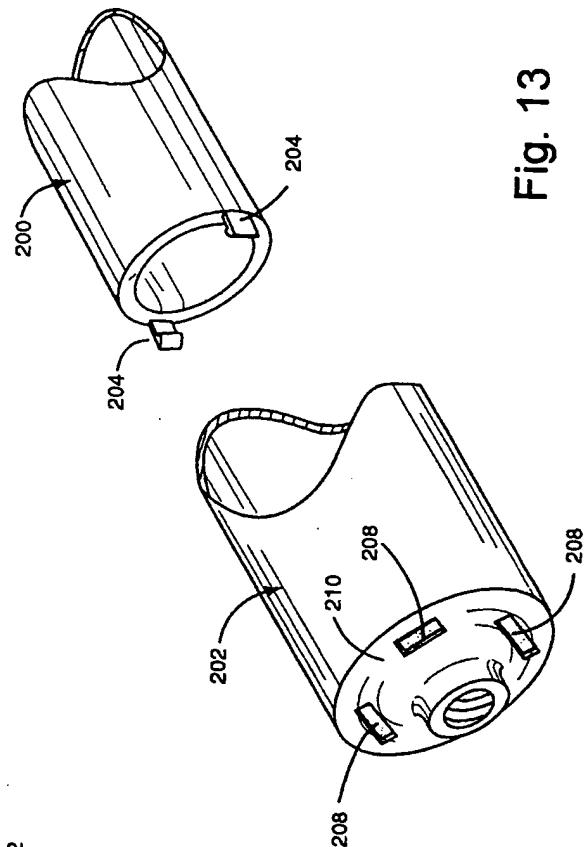
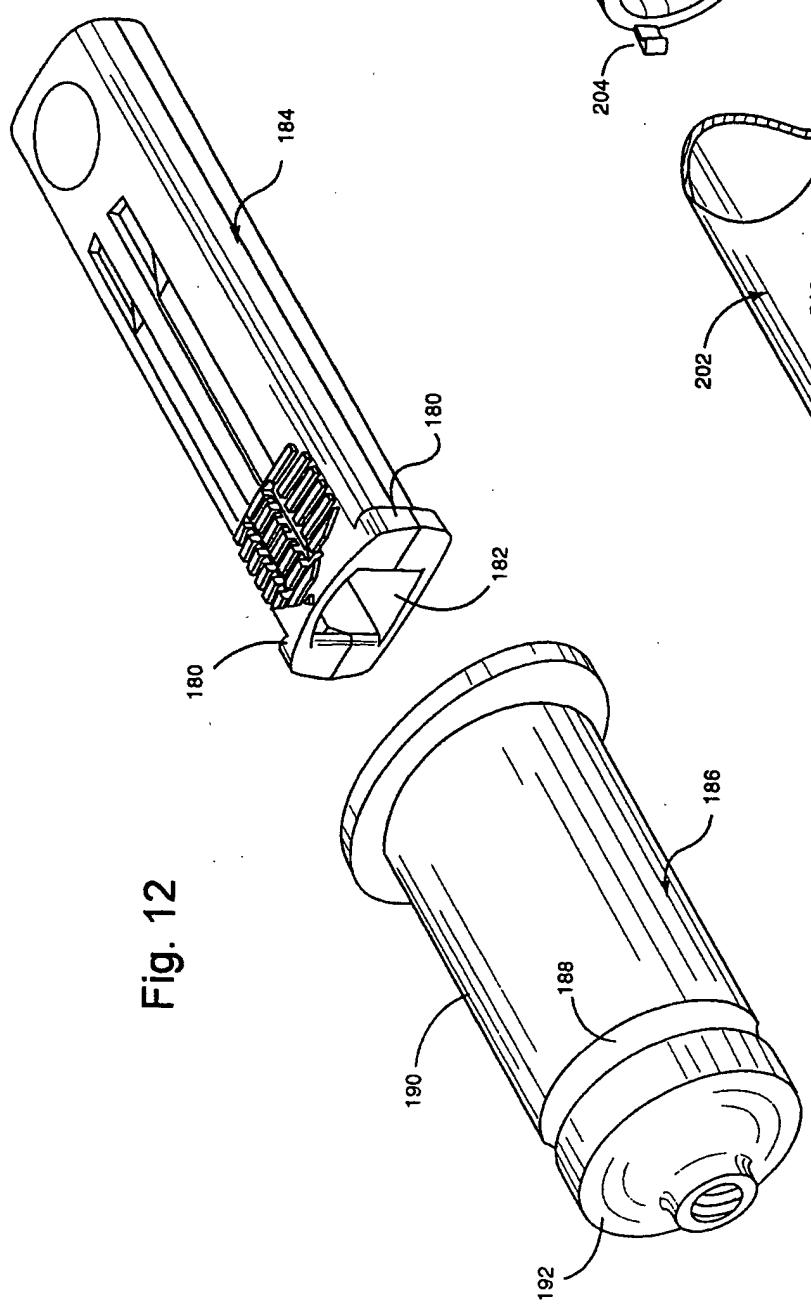


Fig. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00598

A. CLASSIFICATION OF SUBJECT MATTER		
Int Cl ⁶ : A61M 5/162, 5/158, 39/10		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) IPC A61B, A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) WPAT, Japio		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,752,936 A (Chen) 19 May 1998 See figures 3 and 8.	8-14
X	US 5,030,209 A (Wanderer et al) 9 July 1991 See column 6 line 58 column 7 line 21, figure 12	8, 11
X	US 4,932,418 A (Coburn) 12 June 1990 See figures 10, 11, 13-15	14-15
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C		<input checked="" type="checkbox"/> See patent family annex
<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>		
Date of the actual completion of the international search 8 September 1999	Date of mailing of the international search report - 6 OCT 1999	
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929	<p>Authorized officer</p> <p><i>Brendan Bourke</i> BRENDAN BOURKE Telephone No.: (02) 6283 2148</p>	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00598

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,449,539 A (Sarstedt) 22 May 1984 See figures 4, 5	11-13
X	EP 587 347 A (Becton Dickinson and Company) 16 March 1994 See figure 4	14-15
X	DE 42 22 398 A (Wendelborn) 13 January 1994 See stops 25 in figure 1.	14-15
A	US 5,112,311 A (Utterberg et al) 12 May 1992	
A	AU 60601/94 (654464) B (Noble House Group Pty Ltd)	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00598

Box 1**Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II**Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

See attached sheet.

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00598

Box II

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-13 and 16-25 define methods and devices for preventing blood-splash contamination and/or needle-stick injury by inserting the needle guard into the open end of the sample port, as well as needle guards and sampling ports adapted for such a use. It is considered that inserting the open end of the needle guard into the open end of the sample port comprises a first "special technical feature".
2. Claims 14-15 are directed to a sampling port characterised by a stop means to limit the depth to which an evacuated sample phial can be entered such that the phial cannot contact the base of the port. It is considered that the stop means in the sampling port comprises a second "special technical feature". Although claim 14 defines a sampling port "for use in the method of claim 1 or 2", this does not limit the sampling port other than to a sampling port having an open end, which is common to all sampling ports adapted to receive vacutainers.

Since the above-mentioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept.